

REMARKS

The Office Action mailed November 19, 2003, has been received and reviewed. Claims 7 through 31, 57 through 63, 65 and 66 are currently pending and stand rejected. Claims 7, 11, 18, 23, 27, 30, 31, 57, 61-63, 65, and 66 have been amended to more clearly state that which the applicants believe to be his invention and to overcome the rejections raised by the Examiner. Claims 1-6, 10, 13, 32-56, and 64 have been cancelled. With amendment of claims as provided hereinabove, and further in view of the arguments made hereinafter, the applicants contend that Claims 7-9, 11, 12, 14-31, 57-63, 65, and 66 are in condition for allowance and the same is respectfully requested.

Anticipation Rejection of Claims 7, 23, 30 and 57 Under 35 U.S.C. § 102(b)

Claims 7, 23, 30 and 57 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Magruder et al. (U.S. Patent No. 5,690,952), Peery et al. (U.S. Patent No. 5,728,396) or Balaban et al. (U.S. Patent No. 5,456,679) (Office Action, at page 2). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Specifically, the Examiner states that the "cited patents disclose a semipermeable body including a hollow interior portion having a size selected to obtain a predetermined liquid penetration rate through the semipermeable body, the liquid penetration rate for controlling a delivery rate of a beneficial agent." (Office action at pg. 2). Applicants respectfully disagree with the Examiner's reading of Peery et al. and Balaban et al. For example, Peery et al. describes water-swellable semipermeable plugs 24 and 26 (shown in FIGS. 1 and 2) that are inserted into the reservoir. (see, e.g., col. 4, lines 51-54). However, Peery et al. does not describe a hollow interior portion of the semipermeable body having a size selected to obtain a predetermined liquid penetration rate through the semipermeable body. Balaban et al. describes an osmotic

engine that is retained in a semipermeable membrane cup 85, which in turn, is surrounded by a close-fitting sleeve 86 made of rigid material and closed at the end. (see, e.g., col. 8, lines 58-67). Likewise, Balaban et al. does not describe a hollow interior portion of the semipermeable body having a size selected to obtain a predetermined liquid penetration rate through the semipermeable body.

Additionally, neither Magruder et al., Peery et al., or Balaban et al. disclose a semipermeable body that includes a cone-shaped, liquid contact surface for contacting a liquid outside of the osmotic delivery system. As acknowledged by the Examiner, the cited references “do not disclose a conical plug for the infusion of a beneficial agent.” (Office Action at page 3). In view of the foregoing, Applicants respectfully request withdrawal of the Section 102(b) rejections in view of Magruder et al., Peery et al., or Balaban et al.

Rejection of Claims 8-22, 24-29, 31, 58-63, 65 and 66 Under 35 U.S.C. § 103(a)

Claims 8 through 22, 24 through 29, 31, 58 through 63, 65 and 66 stand rejected under 35 U.S.C. § 103 as being unpatentable over Magruder et al. (U.S. Patent No. 5,690,952), Peery et al. (U.S. Patent No. 5,728,396) or Balaban et al. (U.S. Patent No. 5,456,679) in view of Nussbaumer et al. (U.S. Patent No. 4,490,256) (Office Action, at page 2).

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The Applicant submits that the instant invention is not taught or suggested in the prior art. The Federal Circuit has stated that a reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered. *Bausch &*

Lomb, Inc. v. BarnesHind/Hydrocurve, Inc., 230 USPQ 416 (Fed. Cir. 1986). The prior art references cited by the Examiner "would likely *discourage* the art worker from attempting the substitution suggested by [the applicant]." *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923 (Fed. Cir. 1990). The fact that the applicant achieved the claimed invention by doing what those skilled in the art had suggested should not be done is a fact strongly probative of nonobviousness. *Kloster Speedsteel AB v. Crucible Inc.*, 230 USPQ 81 (Fed. Cir. 1986), on rehearing, 231 USPQ 160 (Fed. Cir. 1986). Additionally, "it is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teaching of the prior art so that the claimed invention is rendered obvious One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fritch*, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992).

The Examiner relies on Nussbaumer et al. as teaching the use of a conical and bylindrical plunger for the infusion of fluids in syringes. (Office Action at pg. 3). However, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Nussbaumer et al. is drawn to an apparatus having a conical plunger within a syringe to provide static membrane filtration from solutions. The plunger or piston is movable in the sample vessel (syringe). The syringe "carries at the end face or face facing the vessel bottom a membrane and is mounted in laterally sealed manner in the cylindrical vessel . . ." Second, there must be a reasonable expectation of success. (col. 1, lines 28-34). The apparatus is used for "recovering concentrate and for recovering filtrate. The main field of use is the quantitative recovery of minute concentrate amounts from diluted protein solutions." (col. 2, lines 16-19). "The plunger body 1 is adapted as exactly as possible to the conical end of the syringe. . . . The liquid disposed in the gap 12 and consisting for reasons still to be explained of unconcentrated starting solution thus cannot emerge and dilute the concentrate on removal of the latter." (col. 3, lines 18-29). Thus, Nussbaumer et al. does not teach or suggest an osmotic delivery system plug for controlling delivery rate of a beneficial agent in an osmotic delivery system. In fact, Nussbaumer et al. deals with filtration, which is an entirely unrelated field to osmotic delivery systems. As such, there can be no motivation to combine the arts.

Nussbaumer et al. also does not teach or suggest a semipermeable body at least partially positionable in an opening in an enclosure of an osmotic delivery system, the semipermeable body including a cone-shaped, liquid contact surface for contacting a liquid outside of the osmotic delivery system. In fact, Nussbaumer et al., as illustrated in the preceding paragraph, teaches away from such a concept, since the conical plunger of Nussbaumer et al. is not a semipermeable body and does not form a semipermeable barrier for separating and controlling external liquid from osmotic delivery system. Instead, the conical plunger acts to filter a solution from the gap created at the conical end of the syringe. Thus, the teachings of Nussbaumer et al. would actually *discourage* the art worker from attempting the substitution suggested by the Examiner.

In view of the foregoing amendments and arguments, reconsideration and withdrawal of the Section 103 rejection to claims 8 through 22, 24 through 29, 31, 58 through 63, 65 and 66 is respectfully requested.

CONCLUSION

In view of the foregoing amendments, and further in view of the arguments made, it is believed that this application is now in condition for allowance. Reconsideration and early notice of allowance is respectfully requested.

Respectfully submitted,



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